Oracle Argus Safety Quickhelp for Administrators





Oracle Argus Safety Quickhelp for Administrators, Release 8.4

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Preface

This preface contains the following sections:

- · Documentation accessibility
- · Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Related resources

For information about Oracle Argus patches, see My Oracle Support.

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or onpremises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

Oracle customers that have purchased support have access to electronic support through Support Cloud.

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- English interface of Oracle Health Sciences Customer Support Portal (https:// hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https:// hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.



On-premises customers receive support assistance through My Oracle Support

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Quickhelp for Administrators

To get started with Oracle Argus Safety, you must know how to:

- Manage Access in Oracle Argus Safety
- Disable a User in Oracle Argus Safety

Manage Access in Oracle Argus Safety

You can configure sites, groups, and users from the **Argus Console**. Each user must be assigned to at least one group in order to determine their security level. Each group is assigned a specific security level. This security level enables members of the group to view, modify, or restrict access rights to various sections of the Case Form, and so on.

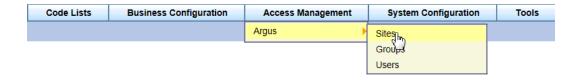
To configure Oracle Argus Safety, begin by creating sites, groups, and users in the following order:

- Add User Sites
- Add User Groups
- Add Users

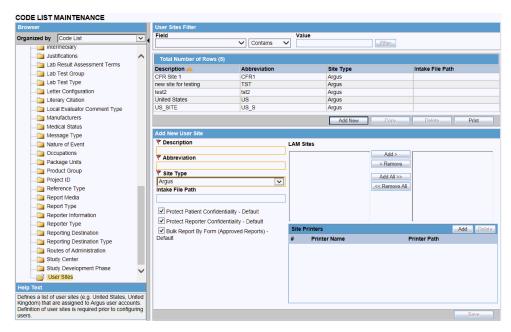
Add User Sites

You must begin by configuring user sites as every user has to be assigned 1 site (and not more). Site information is also used to automatically assign case IDs.

- 1. Log into Oracle Argus Safety and navigate to the Argus Console.
- 2. Hover over the Access Management menu and click Sites.



The **Code List Maintenance** screen is displayed.



- In the left pane, click User Sites.
 The list of users appears in the right pane under Total Number of Rows.
- Click Add New.
 The Add New User Site tab is displayed.
- 5. Enter the required information (fields with a red flag are mandatory) and click **Save**.

Adding User Sites—Fields and Field Descriptions

Field	Description
Description	Enter a description of the site.
Abbreviation	Enter an abbreviation (1-4 characters) of the site name.
Site Type	Select one of the options from the drop-down list: Argus or LAM .



Each Oracle Argus Safety user must be assigned to exactly one user site. You cannot change the site type from **LAM** to **Central** if the current central site has an association with a LAM site, the current site is associated with any user, or the current LAM site has any events assigned to it.

Protect Patient Confidentiality - Default	Select this checkbox to protect patient confidentiality for the site.
Protect Reporter Confidentiality - Default	Select this checkbox to protect reporter confidentiality for the site.



Field	Description
Bulk report By form (Approved reports) - Default	Select this checkbox to protect availability of the bulk reports by form for the site.
LAM Sites	Add or Remove previously created LAM sites using the Add >, Remove <, Add All>>, and Remove All << buttons.
Site Printers	Use the Add and Delete buttons to add/delete the Printer Name, and Printer Path.



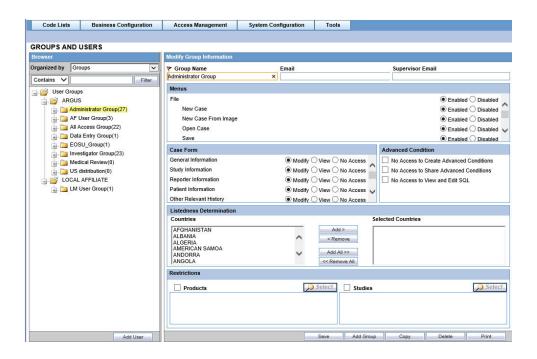
The **Printer Name** is displayed in the application when referring to the printer. The name can have up to 20 characters. For the **Printer Path** textbox, enter the full path of the printer on the network. This path name can have up to 256 characters. The specified path should be accessible from the machine where Argus Safety Service is installed.

Add User Groups

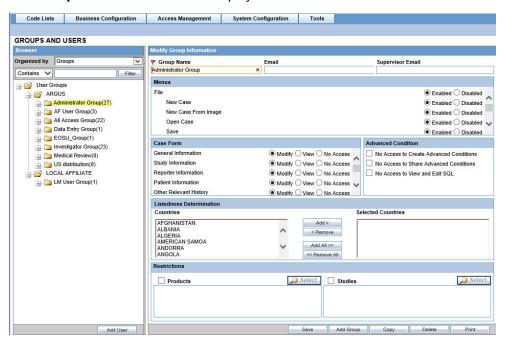
The Administrator can add and configure security levels for each work group. Radio buttons let you view the groups and assign access rights for the **Case Form**, **Menu**, **Case**, and **Report Workflow** sections. If a user belongs to multiple groups, the access rights for the user will be the sum-total of the individual group access rights.

1. Hover over the Access Management menu and click Groups.





The **Groups and Users** screen is displayed.



- In the left pane, click User Groups.
- 3. Click Add Group.
- Enter the required information (fields with a red flag are mandatory) and click Save.

Configuring Users—Fields and Field Descriptions



Field or Control Name	Action
Group Name	Enter a group name. This should be a unique name associated with the group.
Email	Enter the email address, as applicable
Supervisor Email	Enter the supervisor's email address, as applicable.

Menu Descriptions

Menus	Action
File/ New Case/New Case From Image/Open Case and so on	Select the Enable or Disable the options, as applicable.

Case Form Descriptions

Case Form Field or Control Name	Action
General Information/Study Information/Reporter Information and so on	Select Modify, View, or No Access, as applicable.

Advanced Conditions

Advanced Conditions Fields ot Control Name	Action
No Access to Create Advanced Conditions	Select this checkbox if you do not want the group to have access to create advanced conditions.
No Access to Share Advanced Conditions	Select this checkbox if you do not want the group to have access to share advanced conditions.
No Access to View and Edit SQL	Select this checkbox if you do not want the group to have access to view and edit SQL.
Listedness Determination	In the Listedness Determination section, select a list of countries. This enables the end user to override the listedness determination in the Event Assessment section of the Case Form for product licenses that match the countries selected in this step.
	Add or Remove countries using the Add > , Remove < , Add All>> , and Remove All << buttons.
Restrictions -Products	Select the Products checkbox. Click Add Product , to open the Available Products dialog box. Select each product you want to add and click OK .
Restrictions -Studies	Select the Studies checkbox. Click Add Study , to open the Available Studies dialog box. Select each study you want to add and click OK .

Add Users

Ensure that you have provisioned users in IDM before you begin the following procedure.

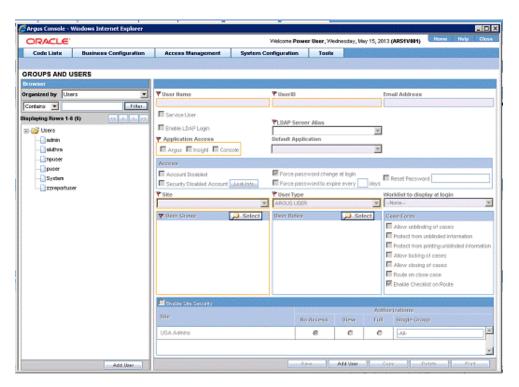
1. Log into Oracle Argus Safety and navigate to the **Argus Console**.



2. Hover over the Access Management menu and click Users.



The **Groups and Users** screen is displayed.



- In the left pane, click Users.The list of users appears in the right pane.
- 4. Click **Add New**. The fields in the right pane become editable.
- 5. Enter the details as needed and click Save.

Configuring Users—Fields and Field Descriptions

Field or Control Name	Description
User Name	Enter the full name.
User ID	Enter unique user identification (ID).
Reset Password	Reset the password of a user to a default value specified in the common profile section.
Email Address	Enter the user's e-mail address.



Field or Control Name	Description
Application Access	Configure user access settings for Argus Console and Oracle Argus Safety.
	The default application access for the user can be selected from the list.
Enable LDAP Login	Authenticates users against the active directory server.
	When Enable LDAP Login is selected, all fields inside the Access section are disabled, excluding the Account Disabled option.
LDAP Server Alias	Click on the drop-down arrow and select the LDAP server which is listed.
Access	Configure user access settings for Oracle Argus Safety. Select the following checkboxes, as applicable:
	Account Disabled
	Forcer Password change at login
	Security Disabled Account
	Force Password to expire every_ days Reset Password
Site	
	Assigns the user to a site. The values in this field are populated from the code list item User Sites.
User Group - Select	Attaches the user to pre-configured user groups.
User Type	Select the type of user, such as, Argus J user from the drop-down list.
User Roles - Select	Attaches the user to pre-configured user roles such as Global Admin . By default, a Global Administrator role is granted only to an Administrator, who can grant/revoke this role to other Argus users. Such a user role must be assigned to users who need access to the Argus Global application. You can also select from other roles present within User Roles .
Enable site security	When this checkbox is checked, site-based data security is enabled for the user. If the box is not checked, the user has full access to data from all sites.
Enable LDAP Login	Authenticates users against the active directory server.
	When Enable LDAP Login is selected, all fields inside the Access section are disabled, excluding the Account Disabled option.
Account Disabled	When this option is selected, the user account is temporarily disabled to prevent users from logging in. This option is different from deleting a user as it enables the Administrator to re-activate the account at a later date.
Security Disabled Account	When unchecked, the login procedure keeps track of the number of consecutive unsuccessful attempts at logging into the system. If the count reaches three, the login procedure will always fail the password validation to lock the user out. Administrators with rights to user maintenance can reset the login attempts for the user to unlock the account. When checked, the login procedure that tracks the consecutive
	unsuccessful attempts at logging into the system do not apply.
Allow unblinding of	Enables the user to unblind a study case.
cases	For example, a user without unblinding rights will not see the Study Drug field. A user with unblinding rights sees a yellow Unblind tag next to the Concentration of Product field, and the Broken by Sponsor option in the Blinding Status drop-down list is enabled.



Field or Control Name	Description
Protect from unblinded Information	When checked, the user cannot view any unblinded information.
Protect from printing unblinded Information	When checked, the user cannot print any unblinded information.
Allow locking of cases	Enables the user to lock/unlock cases.
Allow closing of cases	Enables the user to close cases.
Route on close case	Opens a routing dialog when the user closes the case.
Enable Checklist on Route	By default, this checkbox is selected. If this checkbox is not selected, the checklist for the Workflow is not displayed to the user while routing cases, even if the rule that is being used has a checklist.

Disable a User in Oracle Argus Safety

- 1. Log into Oracle Argus Safety and navigate to the Argus Console.
- 2. Hover over the Access Management menu and click Users. The Groups and Users screen is displayed.
- 3. In the left pane, click **Users**. The list of users appears in the right pane.
- 4. In the Access tab, select Account Disabled and click Save.

